DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission(s) filed on 02/12/2010 and 12/10/2010 have been entered.

Notice of Amendment

2. In response to the amendment filed on 02/12/2010 and entered on 12/10/2010, amended claim(s) 28-30, 32, 34, 42-44, and 47 is/are acknowledged. The current objection(s) and/or rejection(s) is/are *withdrawn*. The following new and/or reiterated ground(s) of rejection is/are set forth:

Drawings

3. The drawings were received on 02/12/2010. These drawings are acceptable.

Claim Rejections - 35 USC § 112 First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28-32,34-38 and 42-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 42 and 43 positively recite "the bristles contact the vaginal wall and obtain the vaginal sample". This claim limitation appears to comprise new matter. Applicant's Specification does not appear to describe, attempt to describe, or distinguish between the relationship between the bristles, the vagina, and the cervix, let alone the "vaginal wall" as claimed.

7. Applicant's Specification explicitly states at least the following:

- "In a preferred aspect, the invention provides a method for detecting HPV in vaginal sample that has been self-collected by the patient in which the sample is substantially few of endocervical cells that has been surprisingly discovered that the presence of endocervical cells is not required for HPV testing, and that **specimens obtained by the self-collection that are composed mainly of cervical epithelial cells are adequate for detecting the presence of HPV**." (Specification page 3 lines 4-8);
- "The present invention further provides methods for detecting the presence of HPV in samples substantially few of endocervical cells. It has been found that endocervical cells are not required for detecting HPV in **a cervical/vaginal specimen, and that a sample consisting of cervical epithelial cells is adequate for detecting HPV and/or for evaluating cervical abnormality**." (Specification page 5 lines 6-9); and
- "In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, **protruding the collection element out to have the bristles**

contact with the cervical/vaginal tissues, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body." (Specification page 6 lines 4-9).

8. Applicant's disclosure is concerned with the cellular makeup of the collected specimen and the structure of the collection device, but does not disclose or attempt to describe, especially to one of skill in the art, the collection of cells on the bristles with respect to any particular location except "the cervical/vaginal tissues". In addition, Applicant's remarks do not appear to indicate where support/enablement of the newly presented claim limitation comprising new matter may be found.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 34-38 and 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallach (US 2002/0120213 A1).

11. Wallach discloses a method for detecting human papilloma virus (HPV) in a self-collected vaginal specimen (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30), said method comprising *inter alia*:

- obtaining the vaginal specimen (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) that contains cervical epithelial cells and few or no endocervical cells (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) (the Examiner notes Wallach is expressly

concerned with gathering the cells from the epithelium layer of the cervix via self-collection by the patient, see paragraph 12) with a device (as best seen in Figure 2) comprising a collection element (15) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) and a shield (20) (as best seen in Figure 2) (paragraphs 22-24 and 27-30) in a form an outer tube (20) (as best seen in Figure 2) (paragraphs 22-24 and 27-30) that surrounds said collection element (as best seen in Figure 2) (paragraphs 22-24 and 27-30),

- wherein said collection element comprises a retractable inner tube (14) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) which is retractable with respect to said outer tube (paragraphs 28-29), and a brush (12) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) attached to said inner tube (as best seen in Figures 1-2),
- wherein said brush and said inner tube have the same longitudinal axis (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30),
- wherein said brush has bristles (11) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) that are substantially perpendicular to the brush longitudinal axis (as best seen in Figures 1-2) (especially when the mop-like flexible bristles are exposed for sampling in a mop-like fashion, paragraphs 22-24 and 27-30),
- wherein the bristles contact the vaginal wall (paragraphs 28-29) and obtain the vaginal sample (paragraphs 28-29),
- wherein the longitudinal axis of said outer tube runs parallel to the longitudinal axis of said inner tube (as best seen in Figure 2),

- wherein the inner tube element and the outer tube element are cylindrical in shape (as best seen in Figure 2),
- wherein an inner tube length and an outer tube length are roughly (i.e. approximately) equal (as best seen in Figure 2),
- wherein the bristles comprise a flexible plastic material (paragraph 24) selected from a group consisting of: polyethylene, polyurethane, polyvinyl chloride, polysiloxanes, and nylon (paragraph 24), and
- wherein the device does not use an absorbent material to collect the vaginal specimen (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30); and

- detecting the presence of HPV (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30), including high risk HPV (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30, especially paragraph 4), in the vaginal specimen through DNA testing (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) without requiring that the specimen contains endocervical cells (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) (the Examiner notes Wallach is expressly concerned with gathering the cells from the epithelium layer of the cervix via self-collection by the patient, see paragraph 12).

12. Furthermore the Examiner notes that the method disclosed by Wallach includes at least the following (although not claimed, Applicant discloses and/or is concerned with the following):

- the distal end of the shield is configured to assist in insertion of the device (paragraphs 11-12),

- the inner tube is covered by the shield during insertion into the patient (paragraphs 11-12),
- the shield and inner tube are moved relative to each other to enable cell sampling by the brush (paragraphs 11-12), and
- the brush and bristles thereon are moved within the patient to aid in the gathering of the cells from the epithelium layer of the cervix vaginal specimen sample cells (paragraphs 11-12).

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach in view of Zavada et al (US 2003/0049828 A1, hereinafter Zavada).

15. Wallach discloses the claimed invention and is expressly concerned with the self collection of cervical epithelial cells for the detection, testing, and analysis of high grade HPV in the DNA of the cervical epithelial cells (paragraphs 4, 5, 11-13, and 30); however, Wallach appears silent with respect to the DNA testing specifics. Wallach discloses the claimed invention, as set forth and cited above, except for expressly disclosing the vaginal specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the vaginal

specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the vaginal specimen.

16. Zavada teaches DNA HPV specimen testing, comprising *inter alia*: (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the vaginal specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the vaginal specimen.

17. All of the biological sample collecting and biological sample diagnostic testing are known in Wallach and Zavada. The only difference is the combination of the biological sample collection and testing into a single invention. It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the biological sample collecting and biological sample diagnostic testing as taught by Wallach with the biological sample diagnostic testing as taught by Zavada to achieve the predictable results of increasing the efficacy of a medical process to effectively and accurately diagnose HPV in a specimen by using well known diagnostic techniques on a collected biological sample.

Response to Arguments

18. Applicant's arguments filed on 02/12/2010 and entered on 12/10/2010 have been fully considered but they are not persuasive.

19. Applicant argues the anticipatory rejection of the claims under Wallach, specifically arguing Wallach does not disclose, teach, and/or fairly suggest

- (a) a method collects cells from the vaginal walls without collecting endocervical cells or
- (b) bristles that are perpendicular to the longitudinal axis of the brush and inner tube.

20. The Examiner respectfully disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

21. The Examiner initially notes that absent any special definition in the instant Specification upon which Applicant does not appear to rely, the claims and terms therein have been treated on the merits consistent with the disclosure under the broadest reasonable interpretation of the limitations therein and using the plain meaning of the terms.

22. As stated by Applicant Wallach is expressly concerned with sampling cervical epithelial cells by rotating exposed mop-like bristles proximate the cervix (see pages 6-7 filed 02/12/2010) (Wallach: abstract and paragraphs 1, 4, 5, 11-13, 21, and 30). This anticipates Applicant's claimed and disclosed invention. Applicant argues that this is contrary to the claim language requiring "the bristles to contact the vaginal wall and obtain the vaginal sample". Applicant's Specification does not positively recite or refer to bristles contacting the "vaginal wall" to obtain the vaginal sample or attempt to distinguish between sampling of the vaginal walls versus the cervix (see above), except to say that endocervical cells are not needed. However and similar to Wallach's disclosure, Applicant's Specification explicitly states at least the following:

- "In a preferred aspect, the invention provides a method for detecting HPV in vaginal sample that has been self-collected by the patient in which the sample is substantially few of endocervical cells that

has been surprisingly discovered that the presence of endocervical cells is not required for HPV testing, and that **specimens obtained by the self-collection that are composed mainly of cervical epithelial cells are adequate for detecting the presence of HPV**." (Specification page 3 lines 4-8);

- "The present invention further provides methods for detecting the presence of HPV in samples substantially few of endocervical cells. It has been found that endocervical cells are not required for detecting HPV in **a cervical/vaginal specimen, and that a sample consisting of cervical epithelial cells is adequate for detecting HPV and/or for evaluating cervical abnormality**." (Specification page 5 lines 6-9); and
- "In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, **protruding the collection element out to have the bristles contact with the cervical/vaginal tissues**, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body." (Specification page 6 lines 4-9).

23. In response to applicant's argument (b) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "bristles that are perpendicular to the inner tube") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

24. In response to applicant's argument that Wallach's bristles are not substantially perpendicular to the longitudinal axis of the brush, the Examiner notes that although Wallach shows the length of the bristles paralleling the longitudinal axis in a direction along the length of the brush (as best seen in Figures 1-2), Wallach is expressly

concerned with configuring the bristles with enough flexibility to perform a mop-like sampling (paragraphs 22-24 and 27-30) and during the mop-like sampling the flexible bristles must bend to assume a mop-like shape which may be fairly and reasonably considered to be at least “substantially perpendicular" to the longitudinal axis of the brush.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey G Hoekstra/
Primary Examiner, Art Unit 3736